K120976
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MAY 23 2012

Links Medical Products Inc.

# 510(k) SUMMARY

**Submitted by:**

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| Owner's Name: | Links Medical Products, Inc. |
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**Contact Person:**

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|---|---|
| Company | NanoSmart, Inc. |
| Address | 29442 Pointe Royale<br>Laguna Niguel, CA 92677 |
| Contact: | James Smith, Ph.D. |
| Telephone | 949-340-7261 |
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| E-mail: | jrsmith00@cox.net |

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| **Date Prepared:** | March 25, 2012 |
| **Trade Name:** | MANUKA IG wound dressings |
| **Common Name:** | Wound Dressing |
| **Classification Name:** | Dressing, Wound, Drug |
| **Device Class:** | Unclassified |
| **Product Code:** | FRO |
| **Predicate Device:** | MANUKAtex Wound Dressing (Manuka Medical, Ltd.) |
| **Predicate 510(k) #:** | K110042 |
| **Device Description:** | MANUKA IG wound dressings are sterile, single-use wound care dressings for use in moist wound management. The primary device is *Leptospermum scoparium* honey from New Zealand impregnated into acetate gauze. MANUKA IG is coated with carboxymethyl cellulose (CMC). The device incorporates 100% active *Leptospermum scoparium* Manuka honey that is harvested and processed under controlled conditions. |

Links Medical Products Inc.

**Intended Use:**

MANUKA IG wound dressings are sterile, single-use wound care dressings for use in moist wound management. MANUKA IG Wound Dressings may be used Over-The-Counter for:

- Minor Abrasions
- Lacerations
- Minor Cuts
- Minor Scalds and Burns

Under the supervision of a healthcare professional, MANUKA IG wound dressings may be used for:

- Leg Ulcers
- Pressure Ulcers
- 1st and 2nd Degree Burns (Superficial and Partial Thickness)
- Diabetic Foot Ulcers
- Surgical Wounds
- Traumatic Wounds

**Technology Comparison:**

The technical characteristics of MANUKA IG wound dressing are substantially equivalent to the predicate device. The devices are similar in function, composition, and intended use. *Leptospermun scoparium* honey is the primary ingredient for MANUKA IG and the predicate device. Both wound dressings incorporate the honey into an absorbent, acetate gauze dressing and have a hydrocolloid surface coating that combines with exudate to assist in dressing removal. Both MANUKA IG and the predicate device are provided as single-use device in individually-sterilized packaging.

**Nonclinical Testing:**

Standard biocompatibility tests were performed on the MANUKA IG wound dressings; including cytotoxicity, intracutaneous reactivity, systemic toxicity, sensitization, and wound healing studies. All tests were performed in accordance with US FDA General Program Memorandum #G95-1 Part-10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North American Science Associates, Inc. (NAMSA). The MANUKA IG wound dressing met the acceptance criteria for all tests conducted and is considered biocompatible under the conditions tested.

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Additional testing included sterilization validation, shelf-life under accelerated and real-time conditions, and packaging validation. All acceptance criteria were met for all tests conducted.

**Conclusion of Comparison:** MANUKA IG and the predicate device were both demonstrated to be biocompatible and meet performance requirements for sterility, shelf-life, and packaging. Based upon technological characteristics and nonclinical performance data, MANUKA IG wound dressings are substantially equivalent and as safe and effective as the currently-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Links Medical Products, Inc
% Nano Smart Incorporated
James Smith, Ph.D. Consultant
29442 Pointe Royale
Laguna Niguel, California 92677

MAY 2 3 2012

Re: K120976
Trade/Device Name: MANUKA IG wound dressings
Regulation Class: Unclassified
Product Code: FRO
Dated: March 27 , 2012
Received: April 02, 2012

Dear Dr. James Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) Number (if known): K120976

Device Name: MANUKA IG wound dressings

Indications for Use:

MANUKA IG wound dressings are sterile, single-use, wound care dressings for use in moist wound management. MANUKA IG wound dressings may be used Over-The-Counter for:

- Minor Abrasions
- Lacerations
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- Surgical Wounds
- Traumatic Wounds

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use X (21 CFR 807 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120976